Assessment of Sensorized Insoles in Balance and Gait in Individuals With Parkinson's Disease

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***Abstract*— Individuals with Parkinson's disease (PD) are characterized by gait and balance disorders limiting their independence and quality of life. Home-based rehabilitation programs, combined with drug therapy, demonstrated to be beneficial in the daily-life activities of PD subjects. Sensorized shoes can extract balance- and gait-related data in home-based scenarios and allow clinicians to monitor subjects' activities. In this study, we verified the capability of a pair of sensorized shoes (including pressure-sensitive insoles and one inertial measurement unit) in assessing ground-level walking and body weight shift exercises. The shoes can potentially be combined with a sensory biofeedback module that provides vibrotactile cues to individuals. Sensorized shoes have been assessed in terms of the capability of detecting relevant gait events (heel strike, flat foot, toe off), estimating spatiotemporal parameters of gait (stance, swing, and double support duration, stride length), estimating gait variables (vertical ground-reaction force, vGRF; coordinate of the center of pressure along the longitudinal axes of the feet, yCoP; and the dorsiflexion angle of the feet, Pitch angle). The assessment compared the outcomes with those extracted from the gold standard equipment, namely force platforms and a motion capture system. Results of this comparison with 9 PD subjects showed an overall median absolute error lower than 0.03 s in detecting the foot-contact, foot-off, and heel-off gait events while performing ground-level walking and lower than 0.15 s in body weight shift exercises. The computation of spatiotemporal parameters of gait showed median errors of 1.62 % of the stance phase duration and 0.002 m of the step length. Regarding the estimation of vGRF, yCoP, and Pitch angle, the median across-subjects Pearson correlation coefficient was 0.90, 0.94, and 0.91, respectively. These results confirm the suitability of the sensorized shoes for quantifying biomechanical features during body weight shift and gait exercises of PD and pave the way to exploit the biofeedback modules of the bidirectional interface in future studies.**

***Index Terms*— Parkinson's Disease, instrumented insoles, plantar pressure, wearable sensors.**

I. INTRODUCTION

PARKINSON'S disease (PD) is a chronic and progressive disease of the brain caused by a deficiency in the neurotransmitter dopamine. This deficiency in the brain's basal ganglia region compromises motor and non-motor subjects' abilities. Consequently to the motor symptoms, people suffering from PD are characterized by gait and balance disorders limiting their independence and quality of life [1]. Typical features of the Parkinsonian gait are small shuffling steps and slowness of movements, i.e., the bradykinetic gait [2], which results in an increment in cadence and double support phase duration concurrently to a reduction of the stride length and walking velocity [3]. In addition, an abnormal distribution of the plantar force [2] and reduced heel-to-toe motion [4] might occur.

PD subjects are usually pharmacologically treated with levodopa, which has been shown to reduce tremors, bradykinesia, and muscle rigidity. However, the aforementioned gait impairments become drug-resistant with the progression of the disease [5]. In combination with drug therapy, rehabilitation programs have been demonstrated to enhance postural stability, muscle strength, and overall functions in daily-life activities [6]. Rehabilitation programs typically include walking overground or on a treadmill, and balance training through body weight-shifting (BWS) exercises [7], [8]. Rehabilitation seems even more effective when subjects commit to training in home settings [9], as this entails a higher volume of training, more realistic training conditions, and lower stress due to traveling to the health facility [10].

The current validated systems to evaluate gait or posturography require a laboratory setting to collect data. Wearable sensing devices are emerging to enable gait and BWS

Manuscript received 6 September 2023; revised 24 January 2024; accepted 19 March 2024. Date of publication 25 March 2024; date of current version 8 April 2024. This work was supported in part by the European Commission under the CYBERLEGs Plus Plus Project (Grant Agreement 731931), within the H2020 Framework. *(A. Pergolini and T. Bowman contributed equally to this work.) (Corresponding authors: A. Pergolini; S. Crea.)*

This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Italian Ministry of Health and the Ethics Committee of Fondazione Don Carlo Gnocchi under Application No. DGDMF.VI/P/I.5.i.m.2/2019/1297, and performed in line with the Declaration of Helsinki.

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Digital Object Identifier 10.1109/TNSRE.2024.3381537

evaluations in home settings. These devices commonly include sensorized shoes to measure ground reaction force and/or detect foot-ground-related events, and inertial measurement units (IMUs), to capture joint kinematics and compute related parameters [11]. With the aim to improve gait, wearable sensory systems can be combined with biofeedback modules to provide users with real-time stimuli based on specific characteristics of the measured biomechanical variables [12], [13], [14]. Numerous prototypes of sensorized shoes have been presented for the gait analysis of partients with PD since the last decade; such prototypes exploit different sensing principles (e.g. capacitive [15], piezoelettric [16], inductive [17], and others), and are based on various algorithms for the estimation of the ground reaction force and computation of gait parameters (e.g. fitting methods, machine learning) [11]. A exhaustive review of the literature in this field has been published recently [12]. Still, despite several works that have been published, the use of wearable biofeedback devices for PD subjects remains an open challenge. A comprehensive evaluation of the different sensorized shoe performances in rehabilitation scenarios, including different types of exercises, is lacking, particularly in assessing and training subjects' balance [18].

We developed a system called Bidirectional Interface (BI), which is a wearable biofeedback device that combines pressure-sensitive insoles and IMUs to detect gait events in real-time and provide concurrent vibrotactile biofeedback according to the gait performance of the user. The device has been preliminarily evaluated with healthy individuals [19].

To use the device in applications with PD subjects, we developed, implemented, and tested real-time algorithms to detect gait events and compute biomechanically-relevant spatiotemporal parameters. In addition, we present the results of a study with PD subjects to investigate the system performance in real-time monitoring and assessing pathological patterns, in walking and balance exercises. We assessed the capability of the BI to detect gait events, describe gait kinematics and kinetics, and compute spatiotemporal parameters of gait that could be used by the physiotherapist to assess the quality of gait of the patient. To the best of our knowledge, this is the first study that proposes a methodology to benchmark a wearable sensory biofeedback system in diverse rehabilitation exercises, including walking and BWS.

II. Materials and Methods

A. BI Architecture

The BI is a wearable vibrotactile biofeedback device, composed of three main modules: (i) a sensing module, consisting of a pair of pressure-sensitive insoles and IMUs; (ii) a mapping module, which is a portable real-time processor and a field-programmable gate array (FPGA) combined with a remote receiver; and (iii) a biofeedback module, constituted by a set of vibrotactile transducers attached to a textile belt (Figure 1). The device has been preliminarly presented and tested with non-disabled individuals in [19].

The pressure-sensitive insoles consist of a matrix of sensing elements, named tactels, based on an optoelectronic technology (patent nr. WO 2013/027145, [20]) engineered for plantar pressure measurement [21]. Each tactel is made of a LED-photodiode pair (OSA Opto Light GmbH, Berlin, Germany; Broadcom Ltd., formerly Avago Technologies Ltd., San Jose, CA, USA) and a deformable silicone cover, shaped like a pyramidal frustum with a square base and an internal curtain. The deformation of the cover due to external force causes the internal curtain to progressively occlude the light path from the emitter to the receiver. Hence, the tactel transduces the force applied on the top surface of the cover into an output voltage measured by the photodiode. Overall, 16 tactels have been distributed over the plantar surface according to an optimization method (patent nr. WO 2021/084427A1, [22]). An electronic board placed on the shoe dorsum acquires the tactel signals and, additionally, integrates a 9-degrees-of-freedom inertial measurement unit (MPU-9250 InvenSense, San Jose, CA, USA). The IMU sensor combines a 3-axis gyroscope and 3-axis accelerometer (MPU-6500, measurement range ±2000deg/s, and ±4g) with a 3-axis digital compass (AK8963). The electronic board has a microcontroller (STM32L476RG, STMicroelectronics, Geneva, CH) that pre-processes sensory signals and manages the transmission of the data to the mapping module. Data are sampled and transmitted at 100 Hz through a wireless Ultra-Wide Band protocol (UWB, DWM1000 DecaWave 6.8 Mbps data rate).

The mapping module is based on two custom electronic boards, i.e. the so-called 'Mezzanine' board and the 'Vibro' board. The Mezzanine manages the wireless communication with the shoe electronic box through a UWB transceiver (DWM1000, DecaWave) and the serial communication to the Vibro board through a standard SPI bus. The VibroBoard houses a System-On-Module SbRIO-9651 (National Instruments, Austin, TX, USA) including the real-time processor and the FPGA (Xilinx Zynq-700, 667 MHz). The FPGA manages SPI communication with the Mezzanine and drives the vibrotactile transducers of the biofeedback module. The real-time processor runs the algorithm for the estimation of the vertical component of the ground reaction force ($vGRF_{Ins}$) and its point of application along the insole longitudinal axes ($yCoP_{Ins}$), the plantar-dorsiflexion angle ($Pitch_{Ins}$), stride length, and velocity. The Vibro board communicates to a laptop via UDP for data visualization and setting of control parameters.

Finally, the biofeedback module is equipped with 6 vibrotactile units placed equally spaced around the waist circumferences, employing an adjustable belt and Velcro strips. The location of the vibrotactile units around the waist circumference was motivated by previous studies showing the perception around the waist to be invariant with gait phases and, therefore, suitable for providing sensory feedback [19].

1) Online Computation of Biomechanical Variables: The output voltages of the tactels are converted into the $vGRF_{Ins}$ following a three-step procedure. First, when the user wears the insoles, a quick de-offset procedure consists of recording the output voltages (offset) of the pressure sensors when the subject has the feet lifted from the ground and then removing such offset from the sensors readings. Such de-offsetting procedure removes the effects of the pressure given by the tightening of the shoe laces. Second, the de-offsetted sensor

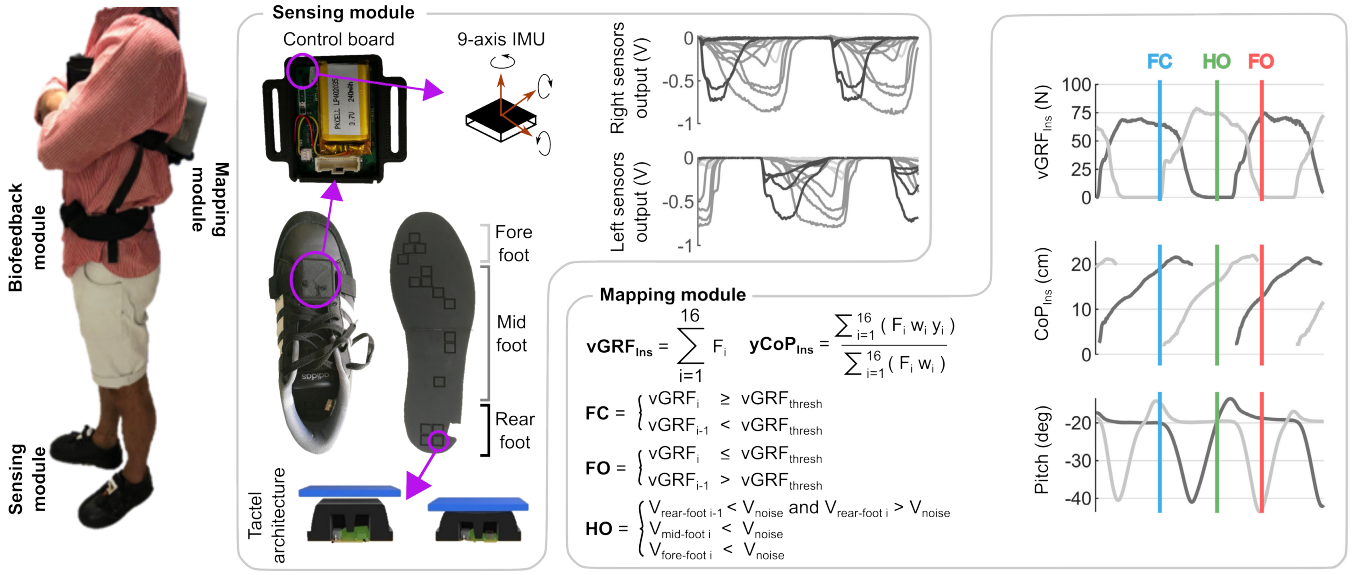

Fig. 1. General architecture of the bidirectional interface device, including three modules, the biofeedback module, the mapping module and the sensing module. The latter includes pressure-sensitive insoles made of custom pressure sensors, called tactless, distributed over the plantar surface, one IMU and a control board. The mapping module computes the vertical component of the ground reaction force ($vGRF_{Ins}$), the center of pressure along the longitudinal axis of the foot ($yCoP_{Ins}$), the planta-dorsiflexion angle ($Pitch_{Ins}$), and runs the control logic for the gait events detection.

readings are input to the characteristic 4th-grade polynomial function, which translates the voltage into a force when the output voltage is lower than a predetermined noise threshold. The polynomial function was extracted through quasi-static load-unload cycles using a universal testing machine (Instron 3400, Illinois Tool Works Inc., Glenview, Illinois, USA) and more details can be found in [23]. Third, when the estimated forces on the tactels exceed a given threshold, the values are summed to compute the $vGRF_{Ins}$, as

$$vGRF_{Ins} = \sum_{i=1}^{16} F_i \quad F_i = \begin{cases} f(Vi), & V_i < V_{noise} \\ 0, & V_i \geq V_{noise} \end{cases}$$

where F_i are the tactel forces (N), V_i are the tactel output negative voltages (V) and V_{noise} is the noise threshold of the output voltage (V).

The $yCoP_{Ins}$ is computed by weighting the force contribution of each sensor by the insole longitudinal coordinate (y_i) and by the tactel spatial density at that coordinate (w_{y_i}) to account for the sensor distribution over the plantar surface:

$$yCoP_{Ins} = \frac{\sum_{i=1}^{16} (F_i \cdot w_{y_i} \cdot y_i)}{\sum_{i=1}^{16} (F_i \cdot w_{y_i})}$$

where y_i are the tactel anteroposterior coordinates (cm) and w_{y_i} are the tactel anteroposterior weights (#). The $yCoP_{Ins}$ is computed only during the stance phase.

The $Pitch_{Ins}$ angle grounds on the gyroscope and accelerometer signals and is computed in real-time through the open-source Madgwick algorithm [24] by integrating the quaternion kinematics equation from the FO to the following FC event detected. To start the integration process, initial conditions were determined using data from the IMUs during the mid-stance phase of walking. The linear acceleration, described in the global coordinates (namely, a reference frame with the z axis aligned with the gravity vector), was first integrated over time to derive the linear velocity. To mitigate drift, a process known as linear de-drifting was applied to the linear velocity at the end of each walking cycle, under the assumption of zero-velocity of the foot. This adjusted linear velocity was further integrated over time to calculate the position of the foot and then the stride length and stride velocity, estimated by determining the foot's position at the end of the integration period.

2) Online Gait Segmentation: The gait cycle is online segmented into phases by means of the detection of three main events: (i) the foot-contact (FC), (ii) the foot-off (FO), and (iii) the heel-off (HO).

The FC and FO events are detected through a threshold-based algorithm applied to the $vGRF_{Ins}$ and by comparing its value in the current iteration (i) to the previous iteration ($i-1$). The threshold value, $vGRF_{thresh}$, was set to 3 N; this value was based on the previous studies with healthy subjects that found it suitable to detect gait events timely and meanwhile avoid misdetections [23]:

$$FC \leftrightarrow \begin{cases} vGRF_i \geq vGRF_{thresh} \\ vGRF_{i-1} < vGRF_{thresh} \end{cases}$$

$$FO \leftrightarrow \begin{cases} vGRF_i \leq vGRF_{thresh} \\ vGRF_{i-1} > vGRF_{thresh} \end{cases}$$

The HO event is detected according to a logic that considers the distribution of the load on the plantar surface and by comparing the load distribution at the current iteration (i) and the previous iteration ($i-1$). The foot can be divided into three areas, the rear-foot, the mid-foot, and the fore-foot (Figure 1), that can be exploited for the detection of the HO event. When the weight becomes entirely distributed on the

mid- and fore-foot, the HO event is detected, as

$$HO \leftrightarrow \begin{cases} \exists V_{rear-foot_{i-1}} < V_{noise} \wedge \forall V_{rear-foot_i} \geq V_{noise} \\ \exists V_{mid-foot_i} < V_{noise} \\ \exists V_{fore-foot_i} < V_{noise} \end{cases}$$

where $V_{rear-foot}$ are the output voltages from each tactels placed on the rear-foot, $V_{mid-foot}$ are the output voltages from each tactels placed on the mid-foot, $V_{fore-foot}$ are the output voltages from each tactels placed on the forefoot and V_{noise} is the noise output voltage threshold.

The gait cycle is segmented in five phases, according to a simplified version of the model proposed by Perry in [25], using the FC HO and FO events computed on both feet, namely: (i) loading response, it corresponds to the initial double-support phase, hence it begins with the one FC and continues until the contralateral FO; (ii) mid stance, it begins with the contralateral FO and ends with the ipsilateral HO; (iii) terminal stance, it begins with the HO and terminates with the contralateral FC; (iv) pre-swing, it corresponds to the final double-support phase, therefore it continues until the FO; (v) swing, it starts with the FO and ends with the next ipsilateral FC.

B. Verification With PD Individuals

The experimental activities aimed to verify the performance of the sensing and mapping modules to detect gait events and estimate biomechanical variables (kinetic and kinematics) that can be used to quantify spatiotemporal paramenters during gait and BWS in PD subjects. Hence, participants were requested to wear the device and perform gait and BWS rehabilitation exercises. The measurements of the wearable system were compared to those of a motion-tracking system (Figure 2).

1) Subjects: The clinical study was approved by the Italian Ministry of Health and by Ethics Committee of Fondazione Don Carlo Gnocchi (DGDMF.VI/P/I.5.i.m.2/2019/1297). The clinical study was conducted in accordance with the principles stated in the declaration of Helsinki. All participants signed a written informed consent prior to the start of the experimentation.

A convenience sample of nine individuals diagnosed with idiopathic PD was included in this study (Table I). Subjects were enrolled from the outpatient/inpatient rehabilitation service of Fondazione Don Carlo Gnocchi (Milano, Italy), based on the following inclusion criteria: (i) Hoehn & Yahr stage of the disease score comprised between 2 and 3 (indicating mild to moderate functional disability with bilateral impairments and postural instability), (ii) Mini-Mental State Exam greater than 24 (indicating the absence of relevant cognitive impairment), (iii) ability to stand still for 30 seconds without assistance and to perform the Timed Up and Go and the 2-minutes Walking test, (iv) stable drug usage, and (v) a shoe size suitable for using the prototype (namely, 41-43 EU). Exclusion criteria were the presence of a deep brain stimulation implant, the necessity to use a walker, and the presence of relevant orthopedic, neurologic, or cardiac comorbidity. Before the start of the experiments, all subjects underwent a clinical evaluation by the neurologist of the clinic and the motor section (section III) of the MDS-Unified Parkinson Disease Rating Scale (MDS-UPDRS) was used to characterize subjects' motor symptoms.

2) Experimental Procedures: All subjects were tested in their ON-medication state, namely one hour after taking their antiparkinsonian medications. Initially, an experimenter helped all subjects to wear the BI and familiarize themselves with the device.

Then, five reflective markers were positioned above the shoes on the hallux tip, the heel, the fifth toe metatarsal, and on the lateral malleolus and sacrum of the participants following a reduced LAMB model protocol [26]. Markers trajectories were recorded with a commercial motion capture (MoCap) system with nine infrared cameras (Smart DX, BTS, Milan, Italy) at a sampling rate of 250 Hz, additionally equipped with four adjacent force platforms that synchronously acquired the kinetic data at 1.6 kHz.

Individuals were requested to perform five tasks, namely ground-level walking and four BWS, as shown in Figure 2. Before the beginning of each task, subjects were instructed to stand still and wait for the instruction of the experimenter to begin the activity; once the task finished, they were also requested to stand still until the experimenter told them to rest.

For each task, an analog trigger signal was sent to the BI and the motion capture system at the beginning and the end of the activity, for the temporal alignment of the recorded signals from the two recording devices.

For the ground-level walking task, subjects were asked to walk at a self-selected speed on a 10-meter straight path that included four force platforms, and within the motion capture system workspace. To avoid inducing alterations in gait patterns, subjects were not explicitly asked to step over the force plates. The task was repeated until at least 3 left and 3 right steps were correctly acquired on the force platforms.

Concerning BWS, subjects were requested to perform medio-olateral, anteroposterior, and craniocaudal BWS exercises. Specifically, medial-lateral BWS was performed by keeping the legs slightly apart in the frontal plane and shifting the weight from one leg to the other, and reaching the monopodalic position (ML BWS, figure 2). Right and left anteroposterior BWS were performed by stepping forward on the right or left leg and reaching the bipodalic position with the weight on the forward leg (AP BWS RX, AP BWS LX). Craniocaudal BWS was performed moving the body weight from the heels to the toes (HEEL-TOE). In these tasks, subjects were asked to move across different force plates. No specific timings were imposed to start and end the repetitions, to avoid increasing the difficulty of the tasks. Each BWS task was performed until three repetitions were recorded correctly by the force plates.

C. Data Analysis

The data collected by the MoCap system were analyzed offline through the Smart Tracker software (BTS, Milan, Italy) to obtain the three-dimensional coordinates of the markers. Then kinetic and kinematic data from the MoCap system,

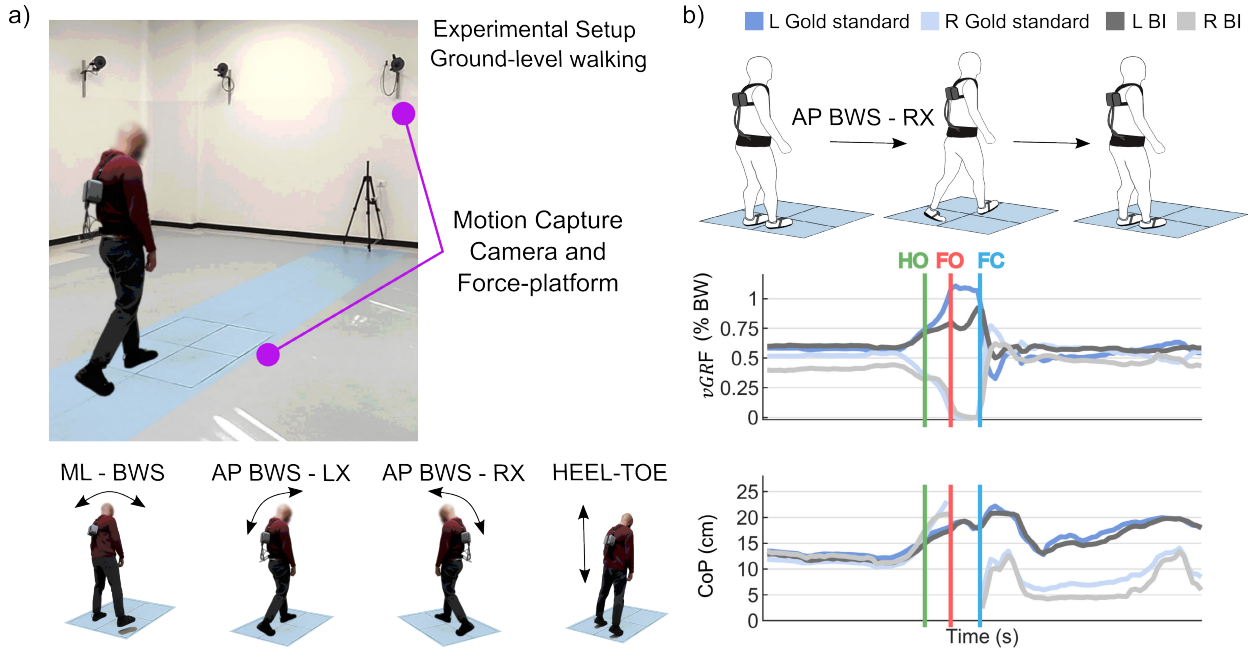

Fig. 2. Experimental setup and procedures. a) Representation of the five tasks, namely, ground-level walking and bodyweight shift (BWS) exercises. Medial-lateral BWS is performed by shifting the weight from one leg to the other and reaching the monopodial position (ML BWS). Right and left anteroposterior BWS are performed by stepping forward the right or left leg and reaching the bipodal position with the weight on the forward leg (AP BWS RX, AP BWS LX). Craniocaudal BWS is performed moving the body weight from the heels to the toes (HEEL-TOE). b) A graphical example of the data acquired from the pressure-sensitive insoles and the force platforms while performing the AP BWS RX task.

TABLE I
DEMOGRAPHIC CHARACTERISTICS OF THE ENROLLED VOLUNTEERS

Subjects	Age (years)	Gender	FoG	Onset (years)	H&Y	MDS-UPDRS	MMSE	Shoe Size(EU)
IDP01	73	Male	yes	19	3	38	28	41
IDP02	59	Male	yes	9	3	33	30	41
IDP03	83	Male	yes	9	3	54	24	42
IDP04	72	Male	yes	4	3	60	26	43
IDP05	76	Male	no	6	2.5	35	27	43
IDP06	73	Male	yes	26	3	53	28	42
IDP07	59	Male	yes	2	2.5	56	28	43
IDP08	75	Male	no	4	2.5	39	29	42
IDP09	79	Male	yes	11	3	68	29	41.5

Abbreviations: FoG, Freezing of Gait; H&Y, Hoehn and Yahr; MDS-UPDRS, Movement Disorder Society-Unified Parkinson Disease Rating Scale; MMSE, Mini-mental state examination; EU, European.

the force platforms, and the BI were processed using custom MATLAB routines (MathWorks, Inc., Natick, MA, USA).

Data acquired by the three systems were temporally aligned by means of the synchronization trigger signal, and low-pass filtered (3^{rd}-order Butterworth anti-causal at 15 Hz for the force platforms, 5^{th}-order at 6 Hz for the motion capture, 2^{nd}-order at 15 Hz for the BI). Strides and BWS not recorded correctly by the force platforms were not included in the analysis. The IMUs data of the BI were then additionally used to estimate the spatial parameters of gait, i.e., stride length, and velocity, following a strap-down integration method [27] and exploiting the online gait segmentation.

MoCap data were processed to compute the ground truth of gait variables and spatiotemporal parameters. The force data recorded by the force plates were processed to compute the point of application (i.e. the center of pressure, CoP) of the ground reaction force along the foot longitudinal direction ($yCoP_{Fpl}$) using the heel and toe markers position and used to segment kinematic data into strides. The FC and FO events were identified by applying a threshold of 30 N on the vertical ground reaction force, as recommended by the manufacturer's software. The HO events were identified from the coordinates of the heel marker using the method described in [28]. For the ground-level walking task, the $Pitch_{MoCap}$ angle,the stride velocity and the stride length were computed as in [29].

Data of both sides, right and left, were aggregated after verifying that there were no statistical differences across the two sides by comparing the right and left stance durations measured by the force plates (Wilcoxon rank sum, $\alpha = 0.05$).

The BI was assessed against the gold standard in terms of (i) accuracy of gait events detection, (ii) accuracy of spatial parameters, (iii) repeatability, and (iv) correlation of biomechanical variables.

Firstly, the accuracy of gait events detection was assessed by means of mean absolute error (MAE, (s)) of the events detected by the BI and the force platforms data as:

$$MAE_X = mean\left(\left|X_{Fpl} - X_{Ins}\right|\right)$$

where X_{Fpl} is the time of the FC, FO, and HO events and of the stance duration detected by the force platforms and the X_{Ins} is the time of the events or stance duration detected by the BI. For the ground-level walking task, the MAE of the three events was also expressed as a percentage of the stance duration measured by the force plates, to facilitate biomechanical interpretation.

Secondly, the accuracy of spatiotemporal parameters was evaluated by computing the error between the BI and gold standard parameters in each stride and then expressed as means and standard deviations [30]. Errors were expressed in m for the stride length, m/s for the stride velocity and in percentage of the gold standard measure for both spatial parameters.

Furthermore, the Bland-Altman plot was used to analyze the agreement between the two measurement methods on the stance duration and the stride length parameters. To compare statistically the metrics extracted with the BI with those extracted from the MoCap, for each subject, we extracted the median values of the stance duration and stride length with the two measurement methods and used a parametric paired t-test ($\alpha = 0.05$). The normality of the samples was verified using the Lilliefors test ($\alpha = 0.05$).

Thirdly, the average repeatability of the biomechanical variables was assessed as the root mean square error (RMSE) of the $vGRF_{Ins}$, $yCoP_{Ins}$ and $Pitch_{Ins}$ for each step against the average variable profile. The same RMSE parameters were computed for the variables extracted from the MoCap. To highlight differences in the repeatability of the two measurement systems, for each subject, we computed the average RMSE value for each measurement system, and then we ran a statistical comparison of the samples using a parametric paired t-test ($\alpha = 0.05$) The normality of the samples was proved with the Lilliefors test ($\alpha = 0.05$).

Lastly, to assess the correlation of the biomechanical profiles, the BI variables, $vGRF_{Ins}$, $yCoP_{Ins}$ and $Pitch_{Ins}$, were compared to the gold standard measures, namely $vGRF_{FPl}$, $yCoP_{FPl}$ and $Pitch_{MoCap}$, by means of the Pearson correlation coefficient.

Concerning the BWS tasks, the repeatability was not evaluated as variable profiles had much higher variability in terms of amplitude and duration. Furthermore, the $Pitch_{Ins}$ angle was not assessed against the motion capture system due to technical problems in acquiring the lateral malleolus and the fifth toe metatarsal markers during the acquisitions.

III. Results

The analysis included 101 strides (51 for the right and 50 for the left foot) of the ground-level walking task and 108 repetitions of the BWS tasks.

Figure 3 shows the results for the ground-level walking tasks. Concerning the gait event detection, the performance of the wearable system showed a median MAE between participants equal to 0.03 s for the FC, and 0.03 s for the FO, corresponding to 3.36%, and 3.83% of the stance duration, respectively. The combination of FC and FO event detection brought to an overall stance duration MAE equal to 0.01 s corresponding to the 1.62 % of the reference stance duration. In addition, the detection of the HO event showed a MAE of 0.03 s corresponding to 3.70% of the reference stance duration (Figure 3 (a)). Concerning the estimation of the stride length and velocity from the BI which uses IMU signals, the median error across participants of -0.002 m was equivalent to 0.25% of the reference stride length, and of -0.001 m/s equivalent to 0.19% of the reference stride velocity (Figure 3 (b)).

Figure 3 (c) shows the biomechanical profiles of a representative participant from the two measurement systems, while the RMSE distribution (namely, the repeatability index) for the yCoP, vGRF, and Pitch angles are shown as boxplots in Figure 3 (d). Across subjects, the statistical comparison between the RMSE computed on the $vGRF_{Ins}$ and $vGRF_{FPl}$ profiles revealed a significant difference between the two devices (p=0.004) equal to 4.86 % BW. The comparison between the RMSE of the center of pressure, namely, $yCoP_{Ins}$ and $yCoP_{FPl}$, showed comparable repeatability between the BI and the force platforms (p=0.969), equal to 0.03 cm. The repeatability index computed for the pitch angle profile, namely, $Pitch_{Ins}$ and $Pitch_{MoCap}$, revealed a significant difference between the two measurement systems (p=0.022), with an absolute difference in terms of RMSE equal to 1.58 deg.

Concerning the Pearson correlation coefficient, results of the $vGRF$, $yCoP$, and Pitch angle were equal to 0.90, 0.94, and 0.91 respectively (Figure 3 (e)).

Regarding the accuracy of spatiotemporal parameters, the Bland-Altman analysis(Figure 4) reported that most of the measurements were within the limits of agreements. The BI computed the stance duration with an average error of 0.01 s, with upper and lower limits of agreements equal to +0.03 s, and -0.04 s respectively. Regression analysis, depicted on the left side of Figure 4 (a), resulted in a coefficient of determination r^2 of 0.99. Concerning the stride length, the BI estimated the parameter with an average error of 0.01 m, with upper and lower limit of agreements equal to +0.16 m, and -0.14 m respectively. Regression analysis, depicted on the left side of Figure 4 (b), resulted in a coefficient of determination r^2 of 0.87. Furthermore, the stride length computed by the BI revealed no statistical difference compared to the one estimated through the MoCap (p=0.948), while stance duration estimation resulted in a statistical difference with a p=0.041.

Figure 5 describes results obtained for the BWS tasks in terms of event detection accuracy and temporal profiles correlation, namely the MAE and Pearson correlation coefficient. Specifically, the MAE for the FC, HO, and FO events was lower than 0.06 s, 0.11 s, and 0.15 s, respectively, in all BWS tasks. Concerning the temporal profiles consistency, the Pearson correlation coefficient of the $yCoP$ was greater than 0.89 in all BWS tasks. Considering the $vGRF$ profiles, the Pearson correlation coefficient was higher than 0.92 for the AP and ML BWS exercises, whereas it was 0.33 in the HEEL-TOE task, with significantly high variability across subjects.

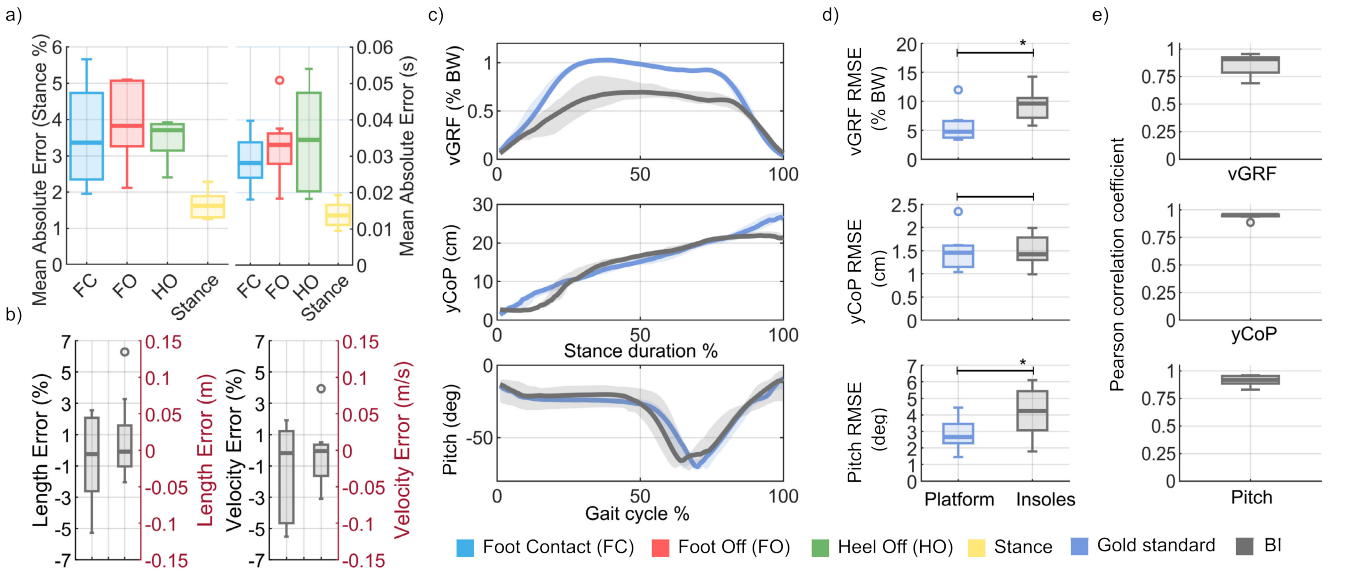

Fig. 3. (a) Accuracy of the gait event detection during walking, expressed in percentage of the stance phase and in seconds. Acronyms: foot contact (FC), foot off (FO), and heel off (HO). (b) Spatial parameters estimation error during walking. Stride length and velocity errors expressed in m and m/s, and as a percentage of the motion capture measurements. Results are shown aggregated between subjects. (c) Median (25th, 75th percentiles) biomechanical profiles estimated by the BI and MoCap from a representative participant. (d) Biomechanical variables repeatability during ground-level walking. Root mean square error (RMSE) between each repetition and the average profile of the ground reaction force (vGRF), the center of pressure (yCoP), and the planta-dorsiflexion angle (Pitch) for both pressure-sensitive insoles and gold standard systems. Results are reported as boxplots across subjects. $*$ shows a statistically significant difference of a paired t-test($\alpha = 0.05$). (e) Correlation of the biomechanical variables computed by the insoles and MoCap in walking.

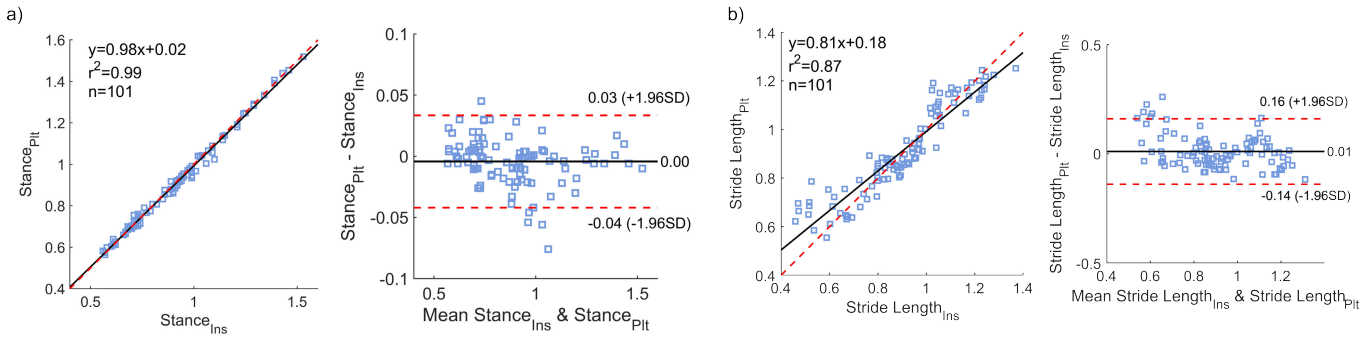

Fig. 4. Bland-Altman plots to quantify the agreement between the sensorized shoes and the gold standard method in the estimation of the stance duration (a) and stride length (b).

IV. Discussion

A. Events Detection

Overground walking of individuals with PD is characterized by low speed and abnormal kinematic and kinetic profiles that make the automatic detection of gait events and consequent computation of spatiotemporal parameters, particularly challenging when using low-resolution and low-power wearable sensors. In this study the pressure-sensitive insoles proved capable of detecting FC, FO, and HO events during overground walking of PD subjects with a temporal MAE lower than 0.03 s for the three events. The MAE was used to evaluate temporal accuracy given its reduced sensitivity to a small number of outliers compared to other metrics.

The results of this study outperformed the results reported in previous investigations in which the same device was tested with healthy subjects, showing a temporal error of 0.06 s on average [23]. Such improvements are particularly remarkable considering the slower walking velocity of PD participants enrolled in this study, as lower walking velocity entails less steep vGRF profiles in the loading response and pre-swing phases. The lowest performance of the wearable system was achieved in detecting the FO event, likely due to the limited number of sensors of the pressure-sensitive insoles under the entire plantar surface. However, in the case of the FO, the MAE was lower than 3.80 % of the stance duration. Furthermore, the analysis of the HO detection, which was evaluated in this study for the first time, showed performance comparable with the other events, therefore proving the system feasible to provide relevant indications on PD gait; in particular, through the detection of the HO event, it is possible to study abnormal conditions in the initiation of gait, that is particularly important in PDs [31] and to segment the gait cycle into phases that are relevant for describing anticipatory postural adjustments [32], [33]. It is important to note that the gait segmentation used in this study exploits bilateral gait information to divide the gait

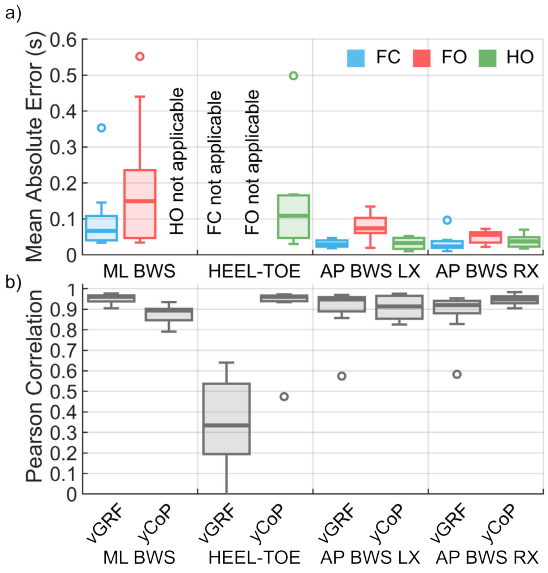

Fig. 5. Gait event detection accuracy and biomechanical variables correlation during body weight shift tasks. Results are reported as boxplots across subjects. (a) Mean absolute Error for the foot-contact (FC), foot-off (FO), and heel-off (HO) events expressed in seconds. (b) Pearson correlation coefficients between the pressure-sensitive insoles ground reaction force (vGRFIns) and center of pressure (yCoPIns) and the force platform measurements.

cycle into phases; in order to simplify the setup and related algorithm, the present method could be easily modified to consider a segmentation of the cyle into four phases using signals gathered from a single limb, which has already been demonstrated to be suitable for gait analysis in subjects with PD in previous studies [34].

Concerning temporal absolute error of events detection, comparable results were achieved while performing AP BWS task. In the ML BWS exercise, instead, the algorithm showed higher median error, likely as a consequence of the sensor distribution over the insole surface that favoured the antero-posterior direction and therefore the detection of events during tasks performed along that direction.

Temporal errors reported in this study are comparable with other state-of-art studies in which pressure-sensitive insoles based on capacitive [35] or piezoresistive [36] sensors were tested in overground walking. Bamberg et al. [16], in a study on a sensorized shoe prototype (called GaitShoe) involving healthy participants and PD subjects, reported a mean error of -0.0065 ± 0.0229 s and -0.0029 ± 0.0169 s in the detection of the heel-strike and toe-off events. The high number and type of sensors in the GaitShoe prototype (including IMU, force-resisting sensors, ultrasound sensors, polyvinylidene fluoride stripes, and others) were exploited for accurate detection of the gait events, but likely increasing the complexity of the sensory system. Overall, it should be noted that, to the authors' knowledge, the present study is the first one in the state of the art that investigated the performance of a sensorized shoe not only in overground walking activities but also in balance exercises including BWS, namely tasks that are performed in the rehabilitation of PD subjects. In this scenario, the system proved feasible for providing an accurate assessment of the subject's capability to perform the walking and balance tasks.

Moreover, the accurate estimation of the stance/swing phases duration (MAE lower than 0.02 s of the stance duration) proposes the pressure-sensitive insoles as a valuable tool for gait's temporal parameters evaluation and to discern differences between PD and healthy gait, as previously done by the PDshoe prototype (stride duration difference of 0.04 s) [37]. Furthermore, these results suggest the suitability of the BI to provide real-time step-synchronized biofeedback similar to what has been done [13], [14] and during BWS tasks.

B. Estimation of Biomechanical Variables

Concerning the estimation of biomechanical variables, the vGRF, the yCoP, and the Pitch profiles measured by the instrumented shoes showed a Pearson correlation coefficient higher than 0.8 in ground-level walking and the AP and ML BWS activities, demonstrating high correlation [38]. The only exception was for the vGRF correlation coefficient in the HEEL-TOE task. In this task, subjects were requested to shift their body weight from the heel to the toe (and vice versa) and repeat the movement without lifting the feet from the ground. Hence, this exercise consisted of a movement within a restricted portion of the foot (across the plantar arch), which is covered by a limited number of sensors and thus reduced the sensitivity of the system significantly in the measurement of the vGRF. Indeed, while the limited portion of the plantar area covered with sensors limits the accuracy of the vGRF estimation in all tasks this limitation is particularly evident in the HEEL-TOE BWS task as the body weight is distributed in the portion of the foot that is covered only by a few sensors. Overall, the limited performance in estimating vGRF profiles is demonstrated by the smaller amplitude of the $vGRF_{Ins}$ than the $vGRF_{FPl}$ (also reported in studies with healthy subjects [23]). This limitation is directly consequent to the tactels number and distribution, as well as to the voltage-to-force computation of forces acting on each tactel, which used the polynomial characteristic equation extracted through quasi-static load-unload cycles. Data-driven model between voltages and force might improve the overall amplitude accuracy of the vGRF estimation but would require subject and/or task specific calibration procedures that may be impractical to repeat in the desired clinical use scenarios.

The agreement between the BI measurements and the force platform reference system is confirmed by the Bland-Altman analysis. In fact, for both stance duration and stride length parameters, the average error results almost zero and the 95.05 % of samples fell within the limits of agreements. Furthermore, both parameters resulted in a high grade of coefficient of determination ($\geq$ 0.87) and the stride length estimation was statistically comparable to the gold standard measurement. These results suggest the suitability of these spatiotemporal parameters for monitoring subjects' activities in walking rehabilitation exercise analysis and open the possibility of exploiting them in the design of biofeedback rehabilitation strategies.

The RMSE was used to assess the measurement repeatability of the yCoP, vGRF and $Pitch_{Ins}$, given its sensitivity to a small number of outliers within a single repetition, as suggested by several studies in the literature. The most

remarkable performance in terms of repeatability was achieved with the yCoP, which was statistically equal to the RMSE of the MoCap. These results confirm the one obtained with healthy subjects [23] and therefore suggest the reliability of the yCoP estimation to be exploited to monitor subjects' activities in rehabilitation exercises and in the design of biofeedback strategies. The variability of the vGRF estimated by the insoles was statistically higher than the force platform measurements, which was probably due to the limited area of the plantar surface covered with sensors. Results are in line with those observed with healthy subjects [23]. Concerning the repeatability of the $Pitch_{Ins}$ angle measurement, the higher variability showed by the BI may be a consequence of the relative motion of the onboard electronics with respect to the shoe dorsum, which may have been additionally compromised by the not-perfect fitting of the shoe size for all the participants. Indeed, the device is limited to a single size of the pressure-sensitive insoles prototype (42 EU), which additionally caused the limited size of the enrolled convenience subjects sample and contributed to the lack of women (together with the double incidence of PD in men [39])

With the aim of making the BI a complete wearable device for home-based rehabilitation, we exploited the shoe-mounted IMU [23], an open-source algorithm [24], and the gait segmentation of the pressure-sensitive insoles to additionally evaluate spatial parameters of gait that are key to evaluate the gait of PD subjects [40]. Results reported in terms of stride-length and stride-velocity estimation error are comparable with the other state-of-the-art devices [16], [41] This opens up the possibility of utilizing the BI for spatial parameter estimationsduring balance activities and rehabilitation exercise with specifically design biofeedback strategies. The capability to estimate the Pitch angle and spatial parameters (in addition to temporal parameters) make the BI a device suitable for use in home-based rehabilitation or to quantify gait performance also with highly compromised gait, with crawling feet, or in presence of specific gait impairments (like freezing of gait events or others). In addition, the combination of the BI with exergames' platforms could be easily implemented and improve subjective acceptability and engagement [42], [43], [44]. These scenarios can involve monitoring, assessing, and training individualized programs for PD subjects. Additionally, the BI sensors' accuracy allows for the analysis other impairments, like freezing of gait events. To this end, it is worth noting that seven of the nine participants enrolled in the study were affected by the freezing of gait; even though the experiments described in this study did not consider any specific analysis about this critical gait impairment of PD.

V. Conclusion

In this study, we assessed the capability of the pressure-sensitive insoles module of the BI to monitor subjects walking and during BWS exercises with the disordered gait of PD subjects. The obtained results suggest the suitability of the prototype to estimate spatiotemporal parameters of PD gait and to analyse biomechanical variables in a sample of subjects with a large variability of motor impairments or deficits, e.g. post-stroke subjects. Furthermore, we presented a methodology to investigate systems performance in real-time monitoring and assessing pathological patterns during walking and balance exercises. Future experiments will assess the capability of the biofeedback module of the prototype in improving the gait of PD and will aim to evaluate the system usability.

Acknowledgment

(Davide Cattaneo and Simona Crea share the senior authorship.)

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Open Access funding provided by 'Scuola Superiore "S.Anna" di Studi Universitari e di Perfezionamento' within the CRUI CARE Agreement